GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

CERTIFICATE NO. : **WC-0034**

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: M/s. Dr. Reddy's Laboratories Ltd., CTO-II,
Plot No.110 & 111, S.V. Co-op, Industrial Estate,
Bollaram (V), Jinnaram Mandal,
Medak Dist, Telangana-502 325, India.

2. Manufacturer's licence number: 91/MD/AP/95/B/R dated 07.12.1989

Regarding the manufacturing plant under (1) of the following Active substance(s) exported to the EU for medicinal products for human use

As per List enclosed as Annexure-1 & 2

The issuing Regulatory Authority hereby confirms that:

The standards of good manufacturing practice applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of Inspection of the plant: 08th & 09th June, 2016.

The Written Confirmation remains valid until: **05th June, 2019**

The authenticity of this written confirmation may be verified with the issuing regulatory authority.

This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority: **Central Drugs Standard Control Organisation**
FDA Bhawan, Kotla Road,
New Delhi- 110 002, India

Name and function of responsible person: Dr. G.N. Singh,
Drugs Controller General (India)

E-mail: dci@nic.in,
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

Federation of Andhra Pradesh Chambers of Commerce & Industry
No. 1030 of 64 - 65
HYDERABAD

ATTESTED

Signature

R. KULKARNI
Joint Director

Stamp of the authority and date

Central Drugs Standard Control Organization
Ministry of Health & Family Welfare

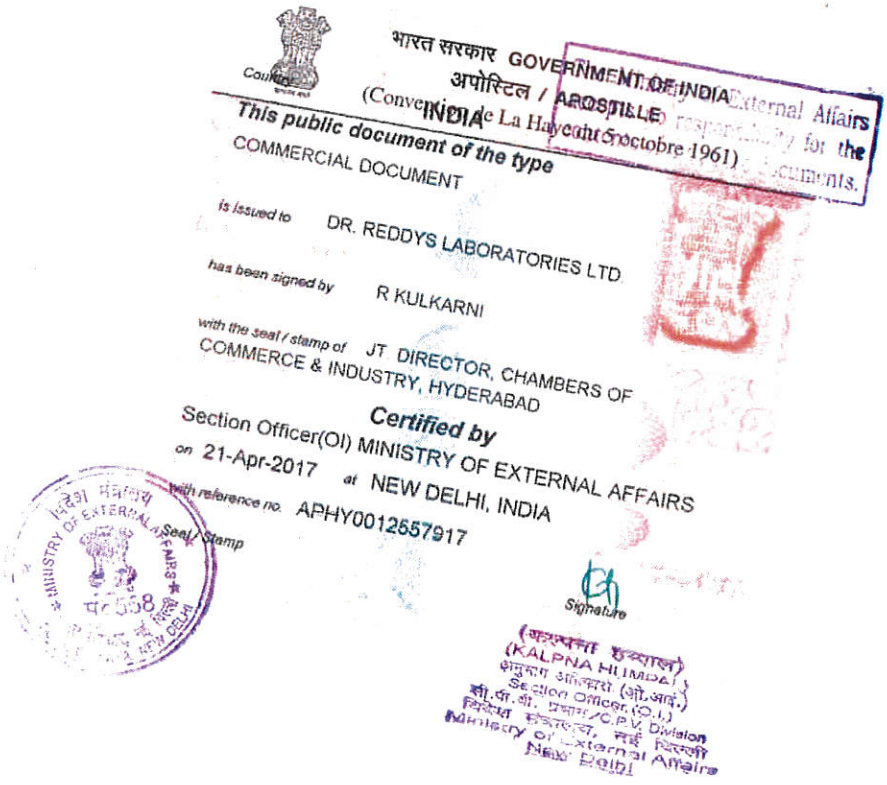
05 AUG 2016

NOTARY AVUTU SAMBI REDDY Regd. No. 4287 Hyderabad-16 INDIA NOTARIAL GOVT. OF INDIA

CERTIFIED AS TRUE COPY OF THE ORIGINAL
by Camscanner

NOTARY AVUTU SAMBI REDDY
NOTARY PUBLIC
Ameerpet, Hyderabad-16.
Telangana. India.
Commission Exp. on July 11, 2017
Regd. No: 4287
GOVT. OF INDIA

18 APR 2017



भारत सरकार GOVERNMENT OF INDIA
अपोस्टिल / APOSTILLE
(Convention de La Haye du 5 octobre 1961)
INDIA

This public document of the type
COMMERCIAL DOCUMENT

is issued to DR. REDDYS LABORATORIES LTD.

has been signed by R KULKARNI

with the seal / stamp of JT. DIRECTOR, CHAMBERS OF COMMERCE & INDUSTRY, HYDERABAD

Certified by
Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS

on 21-Apr-2017 at NEW DELHI, INDIA

with reference no. APHY0012557917

Seal / Stamp

Signature

(कल्पना हुम्मड)
(KALPNA HUMMAD)
अनुभाग अधिकारी (ओ.आई.)
Section Officer (O.I.)
सी.पी.वी. प्रभाग/C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs
New Delhi

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

CERTIFICATE NO. : **Annexure-1**
WC-0034

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: M/s. Dr. Reddy's Laboratories Ltd., CTO-II,
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Medak Dist, Telangana-502 325, India.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Atorvastatin Calcium Trihydrate (IH)	Manufacturing & Packing
2.	Ciprofloxacin (USP/Ph.Eur)	Manufacturing & Packing
3.	Dutasteride (IH)	Manufacturing & Packing
4.	Finasteride (USP/Ph.Eur)	Manufacturing & Packing
5.	Fondaparinux Sodium (IH)	Manufacturing & Packing
6.	Glimepiride (USP/Ph. Eur.)	Manufacturing & Packing
7.	Ketorolac Trometamol (Ph.Eur)	Manufacturing & Packing
8.	Levofloxacin Hemihydrate (IH)	Manufacturing & Packing
9.	Levofloxacin (USP)	Manufacturing & Packing
10.	Moxifloxacin Hydrochloride (USP/Ph.Eur)	Manufacturing & Packing
11.	Raloxifene Hydrochloride (IH/USP/Ph.Eur)	Manufacturing & Packing
12.	Repaglinide (USP/Ph.Eur)	Manufacturing & Packing
13.	Rizatriptan Benzoate (USP/Ph.Eur)	Manufacturing & Packing
14.	Telmisartan (USP/Ph.Eur)	Manufacturing & Packing

ITEM(S) Fourteen (14) ONLY

The Written Confirmation remains valid until: 05th June, 2019

Signature

Chambers of Commerce & Industry of Telangana & Andhra Pradesh
No. 1030 of 64 - 65
HYDERABAD

Stamp of the authority and date

Central Drugs Standard Control Organization
Ministry of Health Family Welfare

05 AUG 2016

ATTESTED

R. KULKARNI
Joint Director

18 APR 2017

NOTARY
AVUTU SAMBI REDDY
Regd. No: 4287
Hyderabad-16
NOTARIAL
GOVT. OF INDIA

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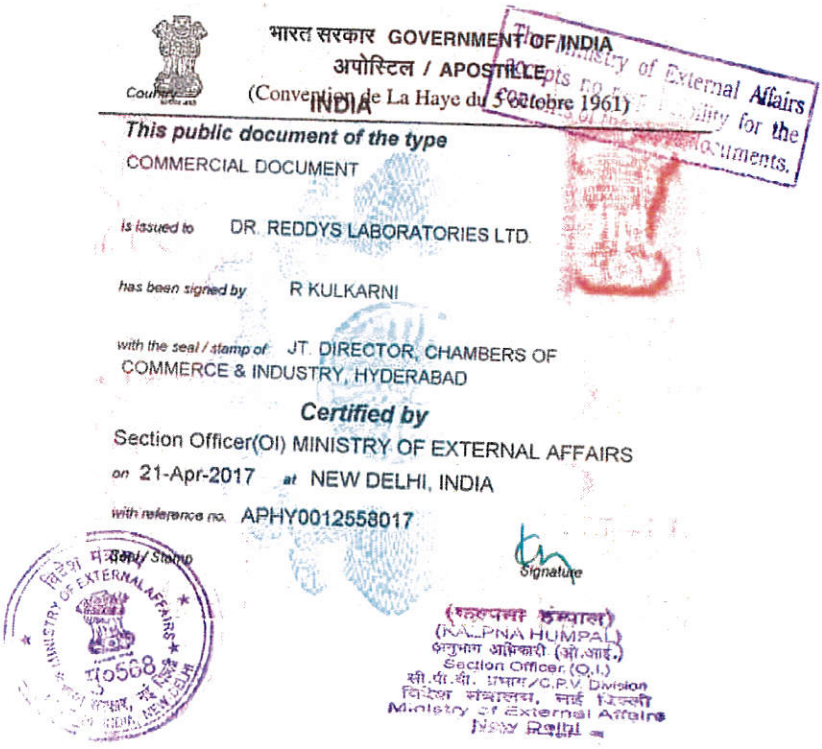

भारत सरकार GOVERNMENT OF INDIA

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Certified by

Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS

on 21-Apr-2017 *at* NEW DELHI, INDIA

with reference no. APHY0012558017

Seal / Stamp

Signature

(कल्पना हुम्पाल)
(KALPNA HUMPAL)
अनुभाग अधिकारी (ओ.आई.)
Section Officer (O.I.)
सी.पी.वी. प्रभाग/C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs
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GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

Annexure-2

CERTIFICATE NO. : WC-0034

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

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Bollaram (V), Jinnaram Mandal,
Medak Dist, Telangana-502 325, India.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Vardenafil Hydrochloride (Ph.Eur)	Manufacturing & Packing

ITEM(S) One (01) ONLY

This certificate is being issued subject to condition that the firm shall obtain NOC from the Competent Authority on case to case basis to manufacture the above mentioned active substance for the purpose of export only, as the above mentioned active substance is not approved for manufacture for sale in India.

The Written Confirmation remains valid until: 05th June, 2019

Signature

Stamp of the authority and date

05 AUG 2016

Chambers of Commerce & Industry of Telangana & Andhra Pradesh
No. 1630 of 64 - 65
HYDERABAD

ATTESTED

R. KULKARNI
Joint Director

18 APR 2017

NOTARY GOVT. OF INDIA
AVUTU SAMBI REDDY
Regd. No: 4287
Hyderabad-16
INDIA
NOTARIAL

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NOTARY PUBLIC
Ameerpet, Hyderabad-16.
Telangana, India.
Commission Exp. on July11, 2017

MEDICO APOSTILLE BANGALORE

भारत सरकार GOVERNMENT OF INDIA

अपोस्टिल / APOSTILLE

(Convention de La Haye du 5 octobre 1961)

Country

INDIA

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Certified by

Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS

on 21-Apr-2017 at NEW DELHI, INDIA

with reference no. APHY0012553117

Seal / Stamp

MINISTRY OF EXTERNAL AFFAIRS * INDIA, NEW DELHI

Signature

(कल्पना हुम्पाल)
(KALPNA HUMPAL)
अनुभाग अधिकारी (ओ.आई.)
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विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs
New Delhi

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